

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board.

Paper No. 25

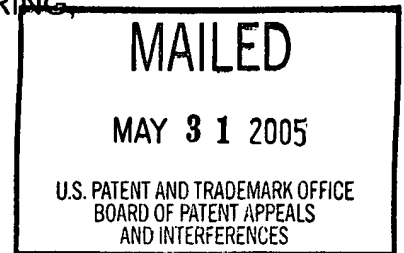
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte HOWARD BERNSTEIN, DONALD CHICKERING,
SARWAT KHATTAK, and JULIE STRAUB

Appeal No. 2004-2221
Application No. 09/731,412

ON BRIEF



Before ELLIS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's
final rejection of claims 20-24 and 27-32.¹ Claim 20 is representative of the
subject matter on appeal, and reads as follows:

20. A method for administering a therapeutic or prophylactic agent comprising
administering to a patient a matrix for delivery of a therapeutic or prophylactic
agent,

wherein the matrix is formed of a biocompatible polymer having
incorporated therein an [sic, a] therapeutic or prophylactic agent and an effective

¹ Claims 20-34 are pending, claims 25, 26, 33 and 34 stand objected to as dependent on a
rejected claim.

amount of a hydrophobic or amphiphilic compound to modify the diffusion of water into the matrix and the release of the therapeutic or prophylactic agent from the matrix, wherein the drug is released over shorter periods of time as compared to release from matrices not incorporating the hydrophobic or amphiphilic compound,

the matrix being formed by a method comprising emulsifying a polymer solution, the therapeutic or prophylactic agent, hydrophobic or amphiphilic compound, and pore forming agent, then removing solvent and pore forming agent to produce a matrix.

The examiner relies upon the following reference:

Gombotz et al. (Gombotz) 5,942,253 Aug. 24, 1999

Claims 20-24 and 27-32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Gombotz. After careful review of the record and consideration of the issue before us, we reverse.

DISCUSSION

According to the rejection,

Gombotz [] teach[es] injection or transmucosal delivery of microparticles comprising polylactic acid or a biadhesive polymer (abstract).

Cellulose is disclosed (column 5 line 21) 0.1%-10% active is specified (column 9 lines 18-19). 4:1 lipid to active is disclosed (column 10 line 7). Phospholipids are specified (column 10 line 8). Pore formers are disclosed (column 9 lines 51-55).

Paper No. 9, pages 2-3.

The examiner does not mention a hydrophobic or amphiphilic compound in the rejection, but in the Examiner's Answer, the examiner states that Gombotz teaches the use of hydrophobic compounds as stabilizers for the active GM-CSF (the therapeutic or prophylactic agent). See Examiner's Answer, page 4.

Appellants argue that Gombotz does not teach the removal of the pore forming agent from the matrix. See Appeal Brief, pages 6-7. While appellants acknowledge that Gombotz discloses pore forming agents, they point out that in methods of preparing the microspheres exemplified by Gombotz, there is no mention of a pore forming agent. See id. at 7. Thus appellants conclude that “[s]ince Gombotz does not disclose each claimed step, and in particular removal of the pore forming agent with the solvent, . . . Gombotz does not anticipate claim 20.” Id. We agree.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). Moreover, in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

Gombotz specifically teaches that “[p]ore forming agents are used to add microstructure to the matrices (i.e., water soluble compounds such as inorganic salts and sugars). They are added as particulates. The range should be between one and thirty percent (w/w, polymer).” Id. at Col. 9, lines 52-55. The disclosure of a w/w range suggests that the pore forming agents, if added, are retained in the microparticle. The examiner points to nothing in the reference, and our review of that reference, did not reveal any teaching or suggestion of removing the pore forming agent. Therefore, the examiner did not meet his

burden of setting forth a prima facie case of anticipation, and the rejection is reversed.

OTHER ISSUES




The instant application has been designated as a divisional of parent application 09/255,179, now U.S. Patent 6,423,345. Appellants noted in the Reply Brief that "the parent application, claiming the matrices per se, were allowed by this same examiner and have now issued as U.S. Patent No. 6,423,345. This patent was allowed over the same art cited against the claims to the method of use of the matrix here on appeal." Id. at 4-5. In response, the examiner noted the reply brief, but did not respond to appellants' comments.

If prosecution is resumed, the examiner should state for the record why if the matrices (products) are patentable, the method of using those matrices are not. Moreover, if the examiner were to issue such a rejection, the rejection would appear to require the signature of the Technology Center Director. Cf. Manual of Patent Examining Procedure (MPEP) § 2307.02 (8th ed., Revision 2, May 2004).

CONCLUSION

Because the examiner failed to set forth a prima facie case of anticipation,
it is reversed.

REVERSED

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Joan Ellis)	
Administrative Patent Judge)	
)	BOARD OF PATENT
Eric Grimes)	
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
Lora Green)	
Administrative Patent Judge)	

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